EUROPEAN
COMMISSION

Brussels, 21.3.2018
C(2018) 1898 final

COMMISSION IMPLEMENTING DECISION

of 21.3.2018

on the transfer of the marketing authorisation granted by Decision C(2004)851 for "Faslodex - Fulvestrant", a medicinal product for human use

(Text with EEA relevance)

(ONLY THE ENGLISH AND SWEDISH TEXTS ARE AUTHENTIC)

COMMISSION IMPLEMENTING DECISION

of 21.3.2018

on the transfer of the marketing authorisation granted by Decision C(2004)851 for "Faslodex - Fulvestrant", a medicinal product for human use

(Text with EEA relevance)

(ONLY THE ENGLISH AND SWEDISH TEXTS ARE AUTHENTIC)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1],

Having regard to Commission Regulation (EC) No 2141/96 of 7 November 1996 concerning the examination of an application for the transfer of a marketing authorisation for a medicinal product falling within the scope of Council Regulation (EEC) No 2309/93[2], and in particular Article 6 thereof,

Having regard to the application submitted by AstraZeneca UK Limited on 21 February 2018 under Article 3 of Regulation (EC) No 2141/96,

Having regard to the opinion of the European Medicines Agency, formulated on 27 February 2018 on the transfer of a marketing authorisation,

Whereas:

(1) The medicinal product "Faslodex - Fulvestrant", entered in the Community register of medicinal products under the number EU/1/03/269 and authorised by Commission Decision C(2004)851 of 10 March 2004, remains in compliance with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3].

(2) A change of holder of the marketing authorisation for which the transfer application is made is a change of an administrative nature, which does not affect the scientific characteristics of the medicinal product already authorised.

(3) It is appropriate to set the date by which all the operations resulting from the transfer of the marketing authorisation must be completed.

(4) The European Medicines Agency has given a favourable opinion.

[1] OJ L 136, 30.4.2004, p. 1.
[2] OJ L 286, 8.11.1996, p. 6.
[3] OJ L 311, 28.11.2001, p. 67.

(5) Decision C(2004)851 should therefore be amended accordingly. The Community Register of Medicinal Products should also be updated.

(6) For the sake of clarity and transparency, it is appropriate, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2004)851 should therefore be replaced.

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation granted by Decision C(2004)851 of 10 March 2004 to AstraZeneca UK Limited for the medicinal product "Faslodex - Fulvestrant", entered in the Community register of medicinal products under No EU/1/03/269, is transferred to AstraZeneca AB.

Article 2

Decision C(2004)851 is amended as follows:

1) Annex I is replaced by the text set out in Annex I to this Decision;

2) Annex II is replaced by the text set out in Annex II to this Decision;

3) Annex III is replaced by the text set out in Annex III to this Decision.

Article 3

1) The transfer referred to in Article 1 shall be authorised from the date of notification of this Decision.

2) All the operations resulting from this transfer must be completed by 30 September 2018 at the latest.

Article 4

This Decision is addressed to:
1. AstraZeneca AB, 151 85 Södertälje, Sverige
and
2. AstraZeneca UK Limited, Charter Way, Macclesfield, Cheshire, SK10 2NA, United Kingdom.

Done at Brussels, 21.3.2018

For the Commission

Xavier PRATS MONNÉ
Director-General

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION